

What Is Claimed Is:

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1. A method of classifying cancer cells in a body fluid sample of a patient with cancer or a patient suspected of having cancer, comprising: isolating circulating cancer cells in the body fluid sample of the patient, and characterizing said circulating cancer cells using cytological and morphological analyses by fluorescence microscopy to determine the classification of the cancer cells isolated, wherein the cancer cell classification comprises terminal cells, proliferative cells, and/or intermediate cells.

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TM A
2. The method of claim 1, wherein at least one cancer cell is a terminal cell that is a fragile, large cancer cell with a large nucleus.

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The method of claim 2, wherein said terminal cancer cell is about 10-50 micrometers in diameter.

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4. The method of claim 1, wherein at least one cancer cell is a terminal cancer cell that is a fragile, large cancer cell without a nucleus.

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5. The method of claim 4, wherein said terminal cancer cell is about 20-40 micrometers in diameter.

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6. The method of claim 1, wherein at least one cancer cell is a terminal cancer cell with a nucleus and biological marker clusters within the cytoplasm.

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7. The method of claim 6, wherein said terminal cell is a late-stage dying cell and is breaking into pieces.

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8. The method of claim 1, wherein at least one cancer cell is a proliferative cancer cell.

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9. The method of claim 8, wherein said cancer cell is about 12-20 micrometers in diameter.

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10. The method of claim 8, wherein said cancer cell is a small proliferative cancer cell that is a dividing cell.

11. The method of claim 1, wherein at least three cancer cells form a microtumor.

12. The method of claim 1, wherein at least one cancer cell is an intermediate cell that is smaller than a terminal cell and larger than a proliferative cell.

13. The method of claim 1, wherein the cancer cells are epithelial cancer cells.

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14. The method of claim 1, wherein the body fluid sample is a natural body fluid sample.

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15. The method of claim 14, wherein said natural body fluid is blood.

16. The method of claim 1, wherein the body fluid sample is a concentrated body fluid sample.

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17. The method of claim 16, wherein said concentrated body fluid is a leukapheresis fraction.

18. The method of claim 1, wherein the cells are isolated using a circulating cancer cell test.

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B6 19. A method of determining the presence or absence of metastatic cancer cells, comprising:

5 (a) isolating circulating cancer cells in a body fluid sample of a patient with cancer or a patient suspected of having cancer;

10 (b) characterizing said isolated cells using cytological and morphological analyses by fluorescence microscopy to distinguish cancer cell classes;

15 (c) determining the classification of the cancer cells isolated, wherein the cancer cell classification comprises terminal cells, proliferative cells, and/or intermediate cells; and

20 (d) assessing whether metastatic cancer is present or absent based on the classification determined in (c).

15 20. The method of claim 19, wherein metastatic cancer is present if the isolated cancer cells are proliferative cells.

Sub
B7 21. A method of determining the efficacy of a medical procedure, comprising:

20 (a) conducting a first isolation of circulating cancer cells in a body fluid sample of a patient with cancer or a patient suspected of having cancer;

25 (b) characterizing said isolated cells using cytological and morphological analyses by fluorescence microscopy to distinguish cancer cell classes;

(c) determining the classification of the cancer cells isolated, wherein the cancer cell classification comprises terminal cells, proliferative cells, and/or intermediate cells;

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(d) conducting a second isolation of circulating cancer cells in a body fluid sample of the patient;

(e) repeating (b) on the cells from the second isolation;

(f) repeating (c) on the cells from the second isolation; and

(g) assessing whether a medical procedure is efficient based on the classification determined in (c) as compared to the classification determined in (f).

10 22. The method of claim 21, wherein the first isolation is conducted before the administration of the medical procedure and the second isolation is conducted after the administration of the medical procedure.

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B8 23. The method of claim 22, wherein the presence of more terminal cancer cells in the second isolation than in the first isolation is indicative of a positive response to the medical procedure.

15 24. The method of claim 22, wherein the presence of more proliferative circulating cancer cells in the second isolation than in the first isolation is indicative of a negative response to the medical procedure.

20 25. The method of claim 21, wherein an increase or no change in the level of circulating cancer cells during or after terminating the medical procedure for a period of time is indicative of a negative response to the medical procedure.

26. The method of claim 21, wherein said medical procedure is selected from the group consisting of surgery, radiation, hormone therapy, gene therapy, and therapeutic agent(s) administration, and a combination thereof.

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